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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/827,432	04/06/2001	Alexandre M. Izmailov	VGEN.P-066	6093
21121	7590	02/25/2004	EXAMINER	
OPPEDAHL AND LARSON LLP			LY, CHEYNE D	
P O BOX 5068			ART UNIT	
DILLON, CO 80435-5068			PAPER NUMBER	
			1631	

DATE MAILED: 02/25/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/827,432

Applicant(s)

IZMAILOV ET AL.

Examiner

Cheyne D Ly

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 May 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-9 is/are pending in the application.
- 4a) Of the above claim(s) 9 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-8 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-9 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 8/01& 7/01 6) ☐ Other: _____

DETAILED ACTION

1. Applicant's election with traversal of Group I, claims 1-8, filed May 16, 2003, is acknowledged.
2. The traversal is on the ground(s) that the Examiner is choosing to make the restriction based on the leaving out the limitation in the apparatus claim that the processor is programmed in a way that mirrors the method steps, the Examiner is not basing the restriction requirement on the apparatus as claimed. Applicant's argument has been fully considered and found to be unpersuasive as discussed below. As recited in the Written Restriction Requirement, mailed March 25, 2003, the Inventions in Groups I and II are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant application, the apparatus of Group II may be utilized in the distinct usages as needed in Group I, a method for alignment of a plurality of data traces indicative of the positions of a plurality of nucleic acid base types in a target nucleic acid, or alternatively, as in standard sequencing only methods with the storage of sequence data without further alignment analysis. It is noted the Written Restriction Requirement does not state that the instant apparatus is only used for standard sequencing methods with the storage of sequence data without further alignment analysis; but as an alternative method to the method of Group I. All of these usages are distinct as requiring distinct and different functions and results thereof without overlapping search due to different subject matter. This lack of overlapping searches documents the undue search burden if they were search together.

3. The requirement is still deemed proper and is therefore made FINAL.
4. The Formal Drawing filed December 16, 2003 has been accepted.
5. Claims 1-8 are examined on the merits.

OBJECTIONS

6. The title of the invention is not descriptive due to the claimed invention is directed to a method with the instant title is directed to a method and apparatus. A new title is required that is clearly indicative of the invention to which the claims are directed.
7. The abstract of the disclosure is objected to because said abstract contains more than 150 words. Correction is required. It is suggested that the new abstract is submitted on a separate sheet of paper. See MPEP § 608.01(b).

IDS

8. Document Tibbetts et al. has not been considered due to the Form 1449 does not list said document with publication information such as publisher and publication date.

CLAIM REJECTIONS - 35 U.S.C. § 112, SECOND PARAGRAPH

9. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

10. Claims 1-8 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
11. Claims 1 and 5 recite the limitation "the sequence" in lines 8-9. There is insufficient antecedent basis for this limitation in the claim. Claims 2-4 and 6-8 are rejected for being dependent from claim 1 or 5.

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12. Claims 1 and 5 recite the limitation "the matching reference" in line 12. There is insufficient antecedent basis for this limitation in the claim. Claims 2-4 and 6-8 are rejected for being dependent from claim 1 or 5.

CLAIM REJECTIONS - 35 USC § 103

13. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

14. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

15. Claims 1-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Giddings et al. (1998) taken with Ewing et al. (1998).

16. Giddings et al. discloses a method via BaseFinder for analyzing trace data from DNA sequencing apparatus (Abstract etc.). The method of Giddings et al. comprises selecting four total wavelengths (4 points) from fluorescent primer based sequencing wherein the "primer peak" is the primer material that is not attached to newly synthesized DNA (unextended primer)

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wherein the trace data is aligned with corresponding position numbers (page 652, column 1, lines 1-4). The BaseFinder is designed to locate the largest peak in the data and the minimum in each of the four channels from the location of the maxima (page 652, column 1, line 9 to column 2, line 5), as in claims 1 and 5, step (a); and claims 4 and 8.

17. The BaseFinder-generated SCF files are processed with Phred for editing of the base-calls and assignment of quality measures to each base and traces go into assembly of a contig based upon six to seven times redundancy in shotgun data, and each base is manually verified and consensus (alignment) is established (page 663, column 2, lines 60 to page 664, column 1, line 13), as instant claims 1 and 5, step (c).

18. The method of Giddings et al. is directed to multiplets of nucleic acid molecules (page 653, column 1, lines 19-22) such as M13mp18 (heterogeneous) (page 659, column 2, last paragraph), as in instant claims 2, 3, 6, and 7.

19. However, Giddings et al. does not disclose the limitation of claims 1 and 5, step (b).

20. Ewing et al. discloses a method of base-calling of trace data using Phred to improve on the quality of sequencing trace data analysis (Abstract etc. and page 184, column 1, Further Improvements §). The base calling algorithm of Ewing et al. comprises the use a phred base-caller to determine the idealized peak locations, the correct number of bases, the observed peaks, observed peaks are matched to the predicted peak locations, and assigning the respective peaks with 1 of the 4 bases to determine a base sequence for the trace (page 176, column 2 to page 177, column 1, Base-Calling Algorithm, Overview §). The algorithm of Ewing et al. comprises comparing the minimum and maximum values of peaks to maximized the number of times a

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peak value is assigned to the predicted peak (page 179, column 1, lines 30-43), as in instant claims 1 and 5, step (b).

21. An artisan of ordinary skill in the art at the time of the instant invention would have been motivated by the improvements disclosed by Ewing et al. (Abstract etc. and page 184, column 1, Further Improvements §) to utilize said improvements in a method for analyzing trace data from DNA sequencing apparatus as taught by Giddings et al. Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention was made to use method for analyzing trace data from DNA sequencing apparatus as taught by Giddings et al. and Ewing et al.

CONCLUSION

22. NO CLAIM IS ALLOWED.

23. Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (see 37 CFR § 1.6(d)). The CM1 Fax Center number is (703) 872-9306.

24. Any inquiry concerning this communication or earlier communications from the examiner should be directed to C. Dune Ly, whose telephone number is (571) 272-0716. The examiner can normally be reached on Monday-Friday from 8 A.M. to 4 P.M.

25. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, Ph.D., can be reached on (571) 272-0722.


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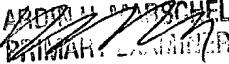
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26. Any inquiry of a general nature or relating to the status of this application should be directed to Legal Instruments Examiner, Tina Plunkett, whose telephone number is (571) 272-0549 or to the Technical Center receptionist whose telephone number is (703) 308-0196.

C. Dune Ly
2/23/04


ARDIN H. MARSCHEL
PRIMARY EXAMINER


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